

**Exactech® Optetrak® 9mm Cruciate Retaining Tibial Insert Slope ++
Special 510(k) - Summary of Safety and Effectiveness**

Sponsor: Exactech® Inc.
2320 N.W. 66th Court
Gainesville, Florida 32653

SEP - 2 2008

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FDA Establishment Number 1038671

Contact: Graham Cuthbert
Regulatory Representative

Date: June 25, 2008

**Exactech® Optetrak® 9mm Cruciate Retaining Tibial Insert Slope ++
Special 510(k) - Summary of Safety and Effectiveness**

Trade or proprietary or model name(s):

Exactech® Optetrak® 9mm Cruciate Retaining Tibial Insert Slope ++

Common Name

Cruciate Retaining Tibial Insert

Classification name

Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal polymer (21 CFR Section 888.3560)

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K932690	Optetrak® Cruciate Retaining Cemented Total Knee System	Exactech, Inc.

Indications for Use:

The OPTETRAK® Comprehensive Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

Device Description:

The proposed Optetrak CR Slope 9mm ++ devices are ultra high molecular weight polyethylene tibial inserts intended to enable surgeons to adjust tibial slope, and therefore PCL function, at the end of a procedure without the need for additional bone cuts. The proposed devices are made from the same materials as the predicated devices. They are also compatible with the same femoral, tibial and patellar components as the cleared predicate devices. The only difference between devices is a +6° posterior angle built into the Optetrak CR Slope 9mm ++ tibial inserts.

Substantial Equivalency Conclusion:

Engineering evaluations were conducted to verify that the performance of the proposed components would be adequate for anticipated *in vivo* use. Based on successful results discussed in this submission, we conclude that the proposed devices are substantially equivalent to the previously cleared predicates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2008

Exactech, Inc.
% Mr. Graham Cuthbert
Regulatory Representative
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K082022

Trade/Device Name: Exactech Optetrak[®] 9 mm Cruciate Retaining Tibial Insert Slope ++
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained
cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: August 20, 2008
Received: August 21, 2008

Dear Mr. Cuthbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exactech® Optetrak® 9mm Cruciate Retaining Tibial Insert Slope ++
Special 510(k) – Indications for Use

510(k) Number: K082022

Device Name: Exactech® Optetrak® 9mm Cruciate Retaining Tibial Insert Slope ++

INDICATIONS FOR USE:

The OPTETRAK® Comprehensive Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

Prescription Use X and/or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K082022